

REMARKS

Claims 26, 36, 37, 42, and 43 are pending in this application. Claim 26 is amended in the manner suggested by the Examiner in the Examiner's Interview Summary dated 8 July 2008.

INTERVIEW SUMMARY

Applicant thanks Examiner Prebilic for the courtesy and assistance provided in the personal interview on 8 July 2008. Applicant submits this Statement of Substance of Interview to summarize the interview in compliance with MPEP §713.04.

Type of Interview: In-person

Names of Participants: Paul Prebilic, Steven Yu

Exhibits: N/A

Claims Discussed: All the pending claims.

References Discussed: The references presently cited against the claims.

Principal Arguments of Applicant: Applicant's representative argued that the claims are compliant with the written description and definiteness requirements of §112. Also, the arguments already made of record were presented.

Agreement: None reached.

REJECTIONS UNDER §112

Claims 26, 36, 37, 42, and 43 stand rejected as being non-compliant with the written description requirement of §112, first paragraph, and the definiteness requirement of §112, second paragraph. Applicant respectfully requests reconsideration.

Applicant respectfully submits that the term "polyfunctional aziridine," as used in claim 36, is known in the art. For example, U.S. Patent No. 5,783,303 to Tsuei (issued 21 July 1998) refers to "a polyfunctional aziridine compound" at col. 5, lns. 52-53. Thus, Applicant respectfully submits that the use of the term "polyfunctional aziridine" does not make the claim indefinite.

Furthermore, as suggested by the Examiner for improving clarity, claim 26 is amended to recite “three or more cross-linking functional groups per molecule.”

For at least these reasons, Applicant respectfully submits that claims 26, 36, 37, 42, and 43 are compliant with the written description and definiteness requirements of § 112. Accordingly, withdrawal of the rejections is respectfully requested.

REJECTIONS UNDER §102

Claims 26, 37, and 43 stand rejected under §102(b) as being anticipated by *Shults et al.* (U.S. Patent No. 4,994,167). Applicant respectfully requests reconsideration of this rejection.

Independent claim 26 specifies that the cross-linking agent has “three or more cross-linking functional groups per molecule.” *Shults* does not disclose this feature.

For at least these reasons, Applicant respectfully submits that *Shults* does not anticipate claims 26, 37, and 43. Accordingly, withdrawal of the rejection is respectfully requested.

REJECTIONS UNDER §103

Claim 36 stands rejected under §103(a) as being rendered obvious by *Shults* in view of *Zhong* (EP 0 728 487) or *Dutta et al.* (U.S. Patent No. 5,529,830). Claim 42 stands rejected under §103(a) as being rendered obvious by *Shults* in view of *Nishimura et al.* (U.S. Patent No. 4,888,285), *Compere et al.* (U.S. Patent No. 4,287,305), or *Guire* (U.S. Patent No. 4,979,959). Applicant respectfully requests reconsideration of these rejections.

Claim 36

The Examiner suggests that it would have been obvious to substitute the cross-linking agent in *Shults* with an aziridine cross-linking agent, such as those described in *Zhong* or *Dutta*. Applicant respectfully disagrees.

Shults describes a biological fluid measuring device for determining the presence and amounts of substances in a biological fluid.¹ One of the components of the *Shults* device is a membrane which acts as a barrier to prevent “direct contact of the fluid sample with the electrodes” while permitting “selected substances of the fluid to pass through the membrane for

¹ *Shults*, Abstract.

electrochemical reaction with the electrodes.”² This membrane can be formed from polyurethane polymers which are cross-linked using a cross-linking agent.³ It is apparent that the device of *Shults* is not intended for use inside of a patient’s body.

As mentioned in the pending Office Action (at pg. 5), the coating composition of *Shults* “contains an excess of polyfunctional crosslinking agent” in order to ensure sufficient reaction completion. Thus, *Shults* uses a conventional technique (i.e., providing a molar excess of a cross-linking agent) to ensure sufficient cross-linking of the polyurethane polymers in the membrane.

By its dependency on claim 26, the coating composition of claim 36 includes a “polyfunctional cross-linking agent [having] three or more cross-linking functional groups per molecule.” By having “three or more cross-linking functional groups per molecule,” unlike *Shults*, the claimed coating composition does not absolutely require a molar excess of the cross-linking agent. Furthermore, because the device of *Shults* is not intended to be used inside a patient’s body, *Shults* has no concern about the leaching of unreacted excess cross-linking agents from the cross-linked polyurethane membrane. As such, *Shults* has no need for a “polyfunctional cross-linking agent [having] three or more cross-linking functional groups per molecule.”

Accordingly, there is no motivation or reason for the modification of *Shults* in the manner suggested by the Office Action. For at least these reasons, Applicant respectfully submits that claim 36 is not rendered obvious by *Shults* in view of *Zhong* or *Dutta*. Accordingly, withdrawal of the rejection is respectfully requested.

Claim 42

With respect to claim 42, the Office Action alleges that *Nishimura*, *Compere*, and *Guire* use a molar excess of a cross-linking agent in order to ensure reaction completion. Therefore, the Office Action states that “it would have been obvious to utilize an excess of cross-linking agent with respect to all organic acid functional groups” of *Shults* for the purpose of ensuring reaction completion.

However, Applicant respectfully points out that using “an excess of cross-linking agent” is not required by the invention of claim 42. In fact, by having multiple functional groups per

² *Shults*, col. 4, lns. 54-58.

³ *Shults*, col. 13, lns. 5-10.

molecule, as in the claimed invention, it is possible to avoid the need for “an excess of cross-linking agent” while still providing sufficient cross-linking functionality to both: (a) cross-link the polycarbonate-polyurethane polymers and (b) react with bioactive agents.

Thus, the claimed invention provides an alternate solution to the problem of ensuring sufficient cross-linking of the polycarbonate-polyurethane polymers, while still having sufficient cross-linking functionality to react with bioactive agents – a solution that does not absolutely require an excess of cross-linking agents, as taught by *Nishimura*, *Compere*, and *Guire*.

None of *Nishimura*, *Compere*, or *Guire* teach or suggest the use of a cross-linking agent having “three or more cross-linking functional groups per molecule” as an alternate solution. For at least these reasons, Applicant respectfully submits that claim 42 is not rendered obvious by *Shults* in view of *Nishimura*, *Compere*, or *Guire*. Accordingly, withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicant respectfully submits that the present application is in condition for allowance. The Examiner is invited to contact Applicant’s representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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